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EXAMINER	
WHITE, EVERETT NMN	
ART UNIT	**PAPER NUMBER**
1623	

DATE MAILED: 05/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/686,918	MARCUM, FRANK D.	
	Examiner	Art Unit	
	EVERETT WHITE	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-36 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-36 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 11/08/04.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

1. Claims 3-5 and 15 are objected to because of the following informalities: The terms "CS4 chondroitin sulfate" and "CS6 chondroitin sulfate" should be changed to their proper chemical names such as - - chondroitin 4-sulfate - - and - - chondroitin 6-sulfate - -. Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-36 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treatment of traumatic synovitis, damaged articular cartilage of a diarthrodial joint, and/or damaged synovial membrane, in man or animals, the specification does not reasonably provide enablement for prevention of traumatic synovitis, damaged articular cartilage of a diarthrodial joint, and/or damaged synovial membrane, in man or animals. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Applicant is entitled to treatment, not "prevention"

The determination that "undue experimentation" would have been needed to make and use the claimed invention is not a single, simple factual determination. Rather, it is a conclusion reached by weighing the factual considerations set forth below in In re Wands, 858 F.2d at 737, 8 USPQ2d at 1404.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue." These factors include, but are not limited to:

(A) The breadth of the claims;

(B) The nature of the invention;

(C) The state of the prior art;

(D) The level of one of ordinary skill;

(E) The level of predictability in the art;

(F) The amount of direction provided by the inventor;

(G) The existence of working examples; and

(H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The breadth of the claims

The breadth of the instant claims is seen to be a method for treatment and prevention of traumatic synovitis, damaged articular cartilage of a diarthrodial joint, and/or damaged synovial membrane, in man or animals by administering a composition. Diarthrodial or synovial joints as described in the instant specification, allows movement and transfer of load between bones. These two critical functions play a major role in athletic performance and disease or injury of these joints, in turn, has a major impact on athletic performance in man and in animals. The instant specification discloses that under normal conditions, the body maintains the synovial joint in state of homeostasis through a variety of complex hormonal and mechanical feedback mechanisms. Two types of insult or injury can upset the delicate homeostatic balance. Repeated trauma or stress (slow chronic insult) to the joint during everyday use, c.g., athletic training or performance, is often the inciting cause of joint inflammation and loss of homeostasis. Initially, such stress results in only soft tissue inflammation in the form of synovitis or capsulitis (c.g., traumatic synovitis). Cartilage damage may or may not initially be present in the early stages of stress related injury or inflammation. However, the release of inflammatory mediators into the joint such as prostaglandins, cytokines, lysosomal enzymes and free radicals can lead to damage of articular cartilage and can cause cartilage degradation and can lead to development of degenerative joint disease. Limitations upon the instant methods as broadly claimed in the instant claims include athletic performance, without sustaining damage or injury associated with traumatic synovitis, damaged articular cartilage of the

diarthrodial joint, and damaged synovial membrane, when the instantly claimed composition is administered to the athlete or animal. This encompasses administration of active agents to healthy patients who subsequently does not obtain traumatic synovitis, damaged articular cartilage of a diarthrodial joint, and/or damaged synovial membrane.

The nature of the invention

The art does not disclose an active agent or combination of active agents, which is recognized as a prevention for the conditions cited supra. The prior art does not teach or disclose a treatment modality wherein healthy subjects are treated with an active agent or agent(s) and there is evidence that none of the associated symptoms or damaged joints characteristics are ever manifested. The disclosure does not direct the skilled artisan to art, which satisfies the requirement for preventing conditions associated with traumatic synovitis, damaged articular cartilage of a diarthrodial joint, and/or damaged synovial membrane.

The state of the prior art

The Henderson patent (US Pat. No. 5,587,363) is cited to show the state of the art which set forth a method for the treatment and reparation of connective tissue in humans and animals, comprising the step of administering a therapeutically effective quantity of a therapeutic synergistic composition including salts of glucosamine in combination with chondroitin sulfate to a human and an animal in need thereof.

The level of one of ordinary skill

The level of skill is that of a MD or PhD.

The level of predictability in the art

Since the art does not disclose any therapeutic preventive compositions, the skilled artisan would not predict, in the absence of proof to the contrary, that the active compositions instantly claimed are efficacious in preventing traumatic synovitis, damaged articular cartilage of a diarthrodial joint, and/or damaged synovial membrane as broadly claimed. The assertion of a broad application as set forth in the instant method claims necessarily requires evidence to support applicant's asserted methods. The examiner notes there are no know compositions recognized as preventive agents

of traumatic synovitis, damaged articular cartilage of a diarthrodial joint, and/or damaged synovial membrane, and one of skill in this art could not predict, from the evidence of record, that the active compositions asserted to be useful in the instantly claimed method, can indeed prevent traumatic synovitis, damaged articular cartilage of a diarthrodial joint, and/or damaged synovial membrane.

The amount of direction provided by the inventor

The examiner notes, there is not seen sufficient guidance provided in the form of administration profiles, combination ratios of the active agents or reference to same in the prior art to provide the skilled artisan with sufficient guidance to practice the instant preventive method. Prevention is seen to encompass administering the active agent to a healthy person or animal, and noting the fact that symptoms of the traumatic synovitis, damaged articular cartilage of a diarthrodial joint, and/or damaged synovial membrane never manifest themselves. The data and evidence provided in the instant disclosure leads the examiner to doubt the objective truth of assertions of prevention of any of the conditions associated with traumatic synovitis, damaged articular cartilage of a diarthrodial joint, and/or damaged synovial membrane.

The existence of working examples

A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. In re Wright, 999 F.2d 1557,1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993). There is not seen in the disclosure, sufficient evidence to support applicant's claims. There is not seen sufficient working examples or data from references of the prior art providing a nexus between that which applicant asserts as proof of a method for or extrapolation from the data and evidence currently provided on the record to support methods drawn to preventing traumatic synovitis, damaged articular cartilage of a diarthrodial joint, and/or damaged synovial membrane.

The quantity of experimentation needed to make or use the invention

More information is needed which clearly shows that the artisan has effectively prevented traumatic synovitis, damaged articular cartilage of a diarthrodial joint, and/or

damaged synovial membrane by administering to a person or animal the instantly claimed composition. It is noted that Law requires that the disclosure of an application shall inform those skilled in the art how to use applicant's alleged discovery, not how to find out how to use it for themselves. See In re Gardner et al. 166 USPQ 138 (CCPA 1970). Therefore, in view of the unpredictability in the art, the lack of working examples, and the lack of guidance in how the skill artisan would use the composition to prevent traumatic synovitis, damaged articular cartilage of a diarthrodial joint, and/or damaged synovial membrane, it would require an undue amount of experimentation to practice the claimed invention.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8 and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In Claims 8 and 9, the metes and bounds of the terms "sterile solution" and "sterile suspension" cannot be determined which renders the claims indefinite since the claims do not clearly set forth what the term sterile is intended to indicate.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Hammerly (US Publication No. US 2001/0046971 A1).

Applicant claims a composition comprising therapeutic amounts of: chondroitin sulfate, N-acetyl D-glucosamine, and hyaluronan.

The Hammerly publication discloses medicinal compositions of matter that comprise a chondropotective component and an analgesic component, wherein the chondroprotective component may be selected from a group comprising chondroitin sulfate, N-acetyl glucosamine, hyaluronic acid and hyaluronan (see paragraph No. 0011 on page 2). See paragraph No. 0017 for the dosage levels of the glucosamine sulfate and chondroitin sulfate, which anticipate the amount of glucosamine sulfate and chondroitin sulfate set forth in the instant claims. The recited use of the composition in the instant claims for the treatment and/or prevention of damaged articular cartilage of a diarthrodial joint and treatment and/or prevention of traumatic synovitis are noted. However, a difference in intended use cannot render a claimed composition novel. Note In re Tuominen, 213 USPQ 89 (CCPA, 1982); *In re Pearson*, 494 F2d 1399; 181 USPQ 641 (CCPA, 1974); and *In re Hack* 114 USPQ 161. The medicinal composition of the Hammerly publication anticipates the composition of the instantly claimed invention since the compositions of the Hammerly publication and instant invention consists essentially of analogous components.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 21-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hammerly (US Publication No. US 2001/0046971 A1) in view of Evans et al (US Publication No. US 2001/0002401 A1).

Applicant claims a method for the treatment and/or prevention of damaged articular cartilage of a diarthrodial joint in man or amimals, comprising administering therapeutic amount of a composition comprised of chondroitin sulfate; N-acetyl D-glucosamine; and hyaluronan. The identical composition is also claimed to be useful in the treatment and/or prevention of damaged synovial membrane, traumatic synovitis, in man or in animals.

The Hammerly publication discloses a procedure for administering a medicinal composition to a patient who is afflicted with osteoarthritis, wherein the medicinal composition comprises a chondropotective component and an analgesic component, wherein the chondroprotective component may be selected from a group comprising chondroitin sulfate, N-acetyl glucosamine, hyaluronic acid and hyaluronan (see paragraph No. 0011 on page 2). The Evans et al publication, which discloses a method of treating or prevention the early stages of degeneration of articular cartilage or suchondral bone in joints of mammals, defines osteoarthritis as the failure of the diarthrodial (movable, synovial-lined) joint. The definition of the osteoarthritis disclosed in the Evans et al publication suggests that the treatment of osteoarthritis in the Hammerly publication embraces the methods of the instantly claimed invention of treating damaged articular cartilage of a diarthrodial joint and treatment of damage synovial membrane or traumatic synovitis in man or animals, which involve (in both cases) administering a composition comprising chondroitin sulfate, N-acetyl D-glucosamine, and hyaluronan. It would have been obvious to one of ordinary skill in the art at the time the invention was made having the Hammerly publication before him to administer a composition comprising chondroitin sulfate, N-acetyl glucosamine, and

hyaluronan to treat damaged articular cartilage of a darthrodial joint or damaged synovial membrane in view of the recognition in the art, as suggested in the Evans et al publication, that osteoarthritis is defined as the failure of the diarthrodial (movable, synovial-line) joint.

Summary

9. All the claims are rejected.

Examiner's Telephone Number, Fax Number, and Other Information

10. For 24 hour access to patent application information 7 days per week, or for filing applications, please visit out website at **www.uspto.gov** and click on the button "Patent Electronic Business Center" for more information.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Everett White whose telephone number is (571) 272-0660. The examiner can normally be reached on Monday-Friday from 9:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson, can be reach on (571) 272-0661. The fax phone number for this Group is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

E. White
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James O. Wilson
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